K032268

DEC 11 2003

BIOMATLANTE

-Confidential-

MBCP pending TM

510(k) Summary of Safety and Effectiveness

This 510(k) Summary for MBCP™ is provided as required per Section 513(1)(3) of the Food, Drug and Cosmetic Act.

1. GENERAL INFORMATION

Submitter's name and adress :	BIOMATLANTE ZA DES IV NATIONS 5, rue Edouard Belin -F- 44360 VIGNEUX DE BRETAGNE France
Contact :	Myriam VINCENT, Chemical Engineer Tel : +33 228 02 00 09 myriamvincent@biomatlante.com
FDA Establishment Number :	not known
Trade Name:	MBCP™
Common Name:	Resorbable Calcium Salt Bone Void Filler
Classification Name :	Resorbable Calcium Salt Bone Void Filler
Product Code :	MQV
CFR Section :	888.3045
Device Panel :	Orthopedic

Summary preparation date : Revised December 9, 2003

2. PREDICATE DEVICES

Product Code	Manufacturer	510(k) #	Product
MQV	Orthovita	K994337	Vitoss
MQV	Sofamor Danek	K020986	Mastergraft
MQV	Interpore International	K990131	ProOsteon 500R

3. DEVICE DESCRIPTION

MBCP™ is a bone graft substitute. MBCP™ is a microporous and macroporous biphasic calcium phosphate ceramic consisting of 60% hydroxyapatite (HA) and 40% beta tricalcium phosphate (β-TCP). MBCP™ is available in granules or blocks.
MBCP™ is provided sterile for single patient use.

510(k) Summary of Safety and Effectiveness

MBCP™ presents a multidirectional interconnected porosity structure, similar to that of human cancellous bone. MBCP™ implant slowly resorbs during the remodeling and bone defect repair process and is progressively replaced with bone and soft tissues. The progressive resorption of MBCP™ resorbable bone void filler is intended to prevent premature resorption.

4. INTENDED USE

MBCP™ is intended for use as a bone void filler for bony voids or gaps of the skeletal system (e.g. extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.
MBCP™ is a bone filler without initial mechanical properties. Therefore rigid fixation techniques may often be recommended.
When packed into a bony site, MBCP™ gradually resorbs and is replaced with bone during the healing process.

5. CONTRAINDICATIONS

MBCP™ has limited initial mechanical properties. Therefore, this product is contraindicated where the device is intended as structural support in the skeletal system.
Conditions representing contraindications include also :

- osteomyelitis
- implantation in necrotic surgical sites
- degenerative bone disease
- intra-articular implantations

6. ADVERSE EFFECTS

Possible adverse effects include but are not limited to :

- Wound complications including hematoma, infection, and other complications that are possible with any surgery
- Incomplete, or lack of, osseous ingrowth into bone void, as is possible with any bone void filler

7. WARNINGS AND PRECAUTIONS

Rigid fixation techniques may be required to assure rigid stabilization of the defect in all planes. Maximum contact between the product and the recipient bone must be established. The implantation in a revision surgical site containing non-resorbable fragments of material (e.g. polyethylene ligament waste, carbon fibers) are not recommended.
As with any surgical procedure, care should be exercised in treating individuals with preexisting conditions that may affect the success of the surgical procedure. This includes (but is not limited

to) individuals with long-term steroidal therapy or treatment acting on the calcium or phosphorus metabolism.

MBCP™ is radiopaque until resorbed. Radiopacity may mask underlying pathological conditions. Radiopacity may also make it difficult to radiographically assess the ingrowth of new bone.

MBCP™ is intended for use by surgeons familiar with bone grafting and rigid fixation techniques.

8. SAFETY AND EFFECTIVENESS SUMMARY

8.1. Chemical safety

Chemical safety of MBCP™ is based on the recognized consensus standard specification, ASTM F 1185-88 (reapproved 1993) Composition of Ceramic Hydroxylapatite for Surgical Implants. MBCP™ conforms to the required specifications for heavy metals trace elements level.

8.2. Biocompatibility

The biocompatibility of HA, β-TCP, mixture of both and MBCP™ is well documented. All these biomaterials have consistently proven to be non toxic, non allergenic, biocompatible and elicits no inflammation. No adverse effect or foreign body reaction have been reported.

8.3. Osseous rehabilitation

Radiological, histological and analytical techniques were used to evaluate the bone ingrowth in surgically created bone defects in the femoral cortices of dogs [1]. After 6 weeks, the bone ingrowth appeared essentially in the cortical part of the implant, invading all implant macropores. After 18 weeks, the entire outer part of the implant was transformed into new cortical bone and bone remodelling was observed.

9. SUBSTANTIAL EQUIVALENCE

The device is substantially equivalent based on similar material characteristics and the same intended use. In addition, animal studies and clinical data with the device support its safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2003

Ms. Myriam VINCENT
Regulatory Affairs Manager
BIOMATLANTE
ZA DES IV NATIONS
5, rue Edouard Belin
–F-44360 VIGNEUX DE BRETAGNE
France

Re: K032268
Trade Name: MBCP
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: October 31, 2003
Received: November 5, 2003

Dear Ms. VINCENT:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MBCP pending TM

Indications for Use

510(k) Number: K032268

Device Name: MBCP pending TM

Indications for Use:

MBCP™ is intended for use as a bone void filler for bony voids or gaps of the skeletal system (e.g. extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.
MBCP™ is a bone filler without initial mechanical properties. Therefore rigid fixation techniques may often be recommended.
When packed into a bony site, MBCP™ gradually resorbs and is replaced with bone during the healing process.

Contraindications:

MBCP™ has limited initial mechanical properties. Therefore, this product is contraindicated where the device is intended as structural support in the skeletal system.
Conditions representing contraindications include also :

- osteomyelitis
- implantation in necrotic surgical sites
- degenerative bone disease
- intra-articular implantations

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over the Counter Use _____

for Mark N. Milkerson

...ion of ...ral, Restorative
Neurological Devices

...) Numb... K032268